



ATTORNEY'S DOCKET NUMBER: 0654101-0018

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Lackie, et al. Examiner:  
Serial Number: 10/690,711 Art Unit:  
Filed: October 22, 2003  
For: SOLID PHASE ASSAY FOR DETECTION OF LIGANDS

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

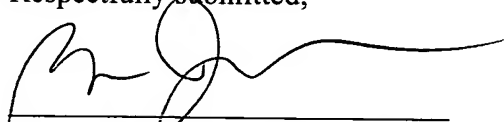
**TRANSMITTAL LETTER**

Enclosed are the following documents:

1. Form PTO-1449 (4 pages);
2. Information Disclosure Statement (4 pages);
3. Cited Art (10); and
4. Return Postcard

If any additional fees are required to be paid or if any overpayment has been made, please charge same to Deposit Account No. 03-1721.

Respectfully submitted,

  
\_\_\_\_\_  
Brenda Herschbach Jarrell, Ph.D.  
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Dated: 1/15/2004



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Lackie, et al. Examiner:  
Serial No.: 10/690,711 Art Unit:  
Filing Date: October 22, 2003  
Title: SOLID PHASE ASSAY FOR DETECTION OF LIGANDS

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**STATEMENT**

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

Type of Statement

The present Information Disclosure Statement is:

- ☒ An *original* Information Disclosure Statement; or  
☐ A *supplemental* Information Disclosure Statement.

**Certificate of Mailing**

I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Sandra Saccocia

\_\_\_\_\_  
Typed or Printed Name of person signing certificate

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

☒ Pursuant to 37 CFR § 1.97(b); no fee or certification is required:

☐ Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);

☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;

☒ Before the mailing of a first Office action on the merits; or

☐ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.

☐ Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *either*:

☐ Certifies that *either*:

☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making

reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; or

☐ Includes herewith the fee set forth in § 1.17(p).

☐ Pursuant to 37 CFR § 1.97(d), after the mailing date of any final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *both*:

☐ Certifies that *either*:

☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; and

☐ Includes herewith the fee set forth in § 1.17(p).

### Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

- ☐ A copy of each cited reference not indicated with an asterisk is included;
- ☒ Copies of references indicated with an asterisk on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status
08/277,225	July 18, 1994	Abandoned

- ☐ Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

- ☐ Does not contain non-English language citations;
- ☐ Does contain non-English language citations, of which the following is a concise explanation:
- ☐ Includes one or more translations of a non-English citation.

### Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b) .

The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

It is respectfully requested that:

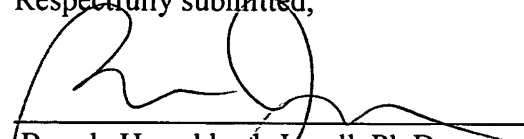
1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Respectfully submitted,

Dated:

1/16/2004



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**FORM PTO-1449** (REV. 8-83) **U.S. Department of Commerce Patent and Trademark Office**

**INFORMATIONAL DISCLOSURE STATEMENT**  
(Use several sheets if necessary)

Atty. Docket:  
0654101-0018

In Re Application No.:  
10/690,711

Applicant: Lackie, et al.

Filing Date:  
October 22, 2003

Group:

**U.S. PATENT DOCUMENTS**

Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass
	*1,716,321	Pearson	June 4, 1929		
	*2,798,718	Gross	July 9, 1957		
	*3,002,092	Cary	September 26, 1961		
	*3,025,142	Williams	March 13, 1962		
	*3,492,396	Dalton, et al.	January 27, 1970		
	*3,600,063	Bowen	August 17, 1971		
	*3,740,552	Pressman	June 19, 1973		
	*4,059,685	Johnson	November 22, 1977		
	*4,115,535	Giaever	September 19, 1978		
	*4,153,675	Klelnerman	May 8, 1979		
	*4,173,392	Ekinaka, et al.	November 6, 1979		
	*4,200,690	Root et al.	April 29, 1980		
	*4,202,665	Wenz et al.	May 13, 1980		
	*4,246,339	Cole et al.	January 20, 1981		
	*4,268,171	Sternberg	May 19, 1981		
	*4,308,026	Mochida et al.	December 29, 1981		
	*4,407,943	Cole et al.	October 4, 1983		
	*4,424,279	Bohn et al.	January 3, 1984		
	*4,425,438	Bauman, et al.	January 10, 1984		
	*4,434,236	Freytag	February 28, 1984		
	4,447,546	Hirschfeld	May 8, 1984		
	*4,454,234	Czerlinski	June 12, 1984		
	*4,459,361	Geftter	July 10, 1984		
	*4,469,787	Woods, et al.	September 4, 1984		
	*4,505,260	Metzger	March 19, 1985		
	*4,582,809	Block, et al.	April 15, 1986		
	*4,585,623	Chandler	April 29, 1986		
	*4,652,533	Jolley	March 24, 1987		
	*4,678,268	Russo, et al.,	July 7, 1987		
	*4,713,347	Mitchell et al.	December 15, 1987		



<b>FORM PTO-1449</b> (REV. 8-83) <b>INFORMATION DISCLOSURE STATEMENT</b> <i>(Use several sheets if necessary)</i>		U.S. Department of Commerce Patent and Trademark Office Atty. Docket: 0654101-0018 In Re Application No.: 10/690,711 Applicant: Lackie, et al. Filing Date: October 22, 2003 Group:	
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	*4,714,345	Schrader	December 22, 1987		
	*4,720,465	Jensen et al.	January 19, 1988		
	*4,721,681	Lentrichia et al.	January 26, 1988		
	*4,775,515	Cottingham	October 4, 1988		
	*4,780,423	Bluestein et al.,	October 25, 1988		
	*4,912,051	Zaromb	March 27, 1990		
	*4,960,692	Lentrichia et al.	October 2, 1990		
	*4,963,498	Hillman, et al.,	October 16, 1990		
	*5,120,643	Ching et al.	June 9, 1992		
	*5,183,740	Ligler, et al.,	February 2, 1993		
	*5,372,783	Lackie	December 13, 1994		
	*5,554,340	Lackie	September 10, 1996		

U.S. PATENT APPLICATIONS					
Examiner's Initials:	Serial Number:	Applicant:	Publication Date:	Group:	Art Unit:

FOREIGN PATENT DOCUMENTS					
Examiner's Initials	Document No.	Country	Date	Translation	
				Yes	No
	*PCT Search Report	PCT	30 May 1995		
	*EP 0206077	EP	09 June 1986		
	*EP 0317286	EP	November 16, 1988		
	*EP 0404258	EP	20 June 1989		
	*GB 2 190 490	UK	18 November 1987		
	*JP 61-20241	Japan	06 September 1986		
	*WO 80/02747	PCT	11 December 1980		
	*WO 89/06799	PCT	27 July 1989		
	*WO 90/07380	PCT	July 12, 1990		
	*WO 93/14403	PCT	22 July 1993		
	*WO 94/03104	PCT	February 17, 1994		

OTHER DOCUMENTS
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FORM PTO-1491 (REV. 8-83) <b>INFORMATION DISCLOSURE STATEMENT</b> (Use several sheets if necessary)		U.S. Department of Commerce Patent and Trademark Office	Atty. Docket: 0654101-0018	In Re Application No.: 10/690,711
			Applicant: Lackie, et al.	
			Filing Date: October 22, 2003	Group:
Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)			
	*Dill, et al., "Antibody-Antigen Binding Constants Determined in Solution-Phase with the Threshold Membrane-Capture System: Binding Constant for Anti-Fluorescein, Anti-Saxitoxin, and Anti-Ricin Antibodies", <i>Anal. Biochem.</i> <b>217</b> : 128, 1994.			
	*Ekins, et al., "Multianalyte Microspot Immunoassay-Microanalytical "Compact Disk" of the Future", <i>Clin. Chem.</i> , <b>37</b> (11): 1955-1967, 1991.			
	*Forrest, et al., "Liposome Enhanced Flow Injection Immunoanalysis", <i>Biotechnology</i> , <b>14</b> :1-11, 1988.			
	*Freytag, et al., "Affinity-Column-Mediated Immunoassays: Influence of Affinity-Column Ligand and Valency of Antibody-Enzyme Conjugates", <i>Clin. Chem.</i> <b>30</b> (9): 1494-1498, 1984.			
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	Glass, et al., "Effect of Numerical Aperture on Signal Level in Cylindrical Waveguide Evanescent Fluorosensors", <i>Applied Optics</i> , <b>26</b> (1): 2181-2187, 1987.			
	*Goldberg, et al., "Methods for Measurement of Antibody/Antigen Based on ELISA and RIA", <i>Curr. Op. Immunol.</i> <b>3</b> : 278, 1993.			
	*Gübitz, et al., "Flow-Injection Immunassays", <i>Analytica Chimica Acta</i> , <b>283</b> : 421-428, 1993.			
	*Gunaratna, et al., "Noncompetitive Flow Injection Immunoassay for a Hapten, $\alpha$ -(Difluoromethyl)ornithine." <i>Anal. Chem.</i> , <b>65</b> : 1152-1157, 1993.			
	Hernando, et al., "An On-Line Immunoassay Method for Theophylline Using a Protein A Immunoreactor", <i>Journal of Pharmaceutical &amp; Biomedical Analysis</i> , <b>9</b> (10-12): 1121-1123, 1991.			
	*Hudson, "Infrared Systems Engineering", Wiley-Interscience, 1969.			
	*Jolley, et al., "Particle Concentration Fluorescence Immunoassay (PCFIA): A New, Rapid Immunoassay Technique with High Sensitivity", <b>21</b> ,			
	Liu, et al., "Flow Injection Solid-Phase Chemiluminescent Immunoassay Using a Membrane-Based Reactor", <i>Analytical Chem.</i> , <b>63</b> (7): 656-659, 1991.			
	*O'Shannessy, et al., Determination of Rate and Equilibrium Binding Constants for Macromolecular Interactions Using Surface Plasmon Resonance: Use of Nonlinear Least Squares Analysis Methods", <i>Anal. Biochem.</i> , <b>212</b> : 457-468, 1993.			
	*Perceptive Biosystems, "ID <sup>TM</sup> Real-Time Immunoassay", Product Report, and Prec. 1st, July			

<b>FORM PTO-144P E</b> (REV. 8-83) <b>INFORMATION DISCLOSURE STATEMENT</b> (Use several sheets if necessary)	U.S. Department of Commerce Patent and Trademark Office		Atty. Docket: 0654101-0018	In Re Application No.: 10/690,711
	Applicant: Lackie, et al.			
	Filing Date: October 22, 2003		Group:	

1992.

\*Plant, et al., "Liposome Enhanced Flow Injection Immunoanalysis", *Biotechnology*, **6**: 1988.

\*Pollema, et al., "Flow Injection Renewable Surface Immunoassay: A New Approach to Immunoanalysis with Fluorescence Detection", *Anal. Chem.*, 1825-1831, 1994.

\*Pollema, et al., "Sequential Injection Immunoassay Utilizing Immunomagnetic Beads", *Anal. Chem.* **64**: 1356-1361, 1992.

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\*Sambucetti, et al., "Process for Purification of Magnetic Ink", *IBM Technical Disclose Bulletin*, **18**(2): 593-595, July 1975.

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Shellum, et al., "Flow-Injection Immunoassays with Acridinium Ester-Based Chemiluminescence Detection", *Analytica Chimica Acta*, **227**: 97-107, 1989.

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\*Skubitz, et al., "Determination of Antibody-Hapten Association Kinetics: A Simplified Experimental Approach", *Jour. of Immunology*, **114**(4): 1975.

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\*Smith, "Modern Optical Engineering. The Design of Optical Systems", McGraw-Hill Inc. (pubs) ©1966.

\*Warden, et al., "Repetitive Hit-and-Run Fluoroimmunoassay for T-2 Toxin", *Analytical Biochemistry* **162**: 363-369, 1987.

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.